

PROSPECTIVE STUDY OF MEDICAL THERAPY AGAINST CRYOBALLOON ABLATION
IN PATIENTS WITH SYMPTOMATIC RECENT ONSET PERSISTENT ATRIAL
FIBRILLATION: METACSA

Final report METACSA

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METACSA is a randomised trial comparing cryoballoon ablation with AAD drugs (after cardioversion) in persistent atrial fibrillation with a duration less than 1 year and no comorbidity.

The study started on 15/12/2015 (first inclusion) and a total number of 13 patients were included (3 centers: UZ Ghent 8, St Jan Brussels 3, and St Luc UCL Brussels, 1, with one excluded patient because of protocol violation).

It concerned 11 men and 1 women. The mean age was 62 years.

All patient had persistent AF, in agreement with the definition. Randomisation was towards ablation for 4 (25%) and towards antiarrhythmic drugs in 8 patients (75%), in spite of block randomisation.

There was cross-over to ablation in 3 AAD patients (once for clinical complaints without documented AF). A total number of 3 ablation patients were taking AAD at one year.

During the follow - up we had one pericarditis observed in the ablation group. One patient in the ablation group had nasal bleeding on Pradaxa. No patient died, all were followed until one year.

At 12 months, sinus rhythm was present in 11/12 (%). Over the observation period, there were 5 patients having recurrences of atrial fibrillation (paroxysmal in 4, persistent in 1). This was in 2/4 of the ablation group and in 3/8 of the AAD group (intention to treat). When we observed the study in OTA, 4/7 ablated patients had recurrences.

The trial had a too low inclusion rate, and the local environment had a tendency to promote ablation, rather than to analyse whether it was necessary. Cross over was performed too easily. Problems with the provider of the digital case report form (suggested by Medtronic) killed the trial as we decided to wait locally for renewed inclusion until this was ready.

The results were in line of the expectations, but as it concerns early inclusions with very small numbers, it is not certain that the entire study would have had a similar outcome. Anyhow, the feasibility was proven.